



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	CLASSIFICATION	ATTORNEY DOCKET NO.
09/655,710	09/05/00	KHANUJA	S	056859/0107 ^{KM}

HM12/0430

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EXAMINER

COE, S

ART UNIT	PAPER NUMBER
1651	7

DATE MAILED: 04/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/655,710

Applicant(s)

KHANUJA ET AL.

Examiner

Susan Coe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 16 April 2001.
- 2a) This action is FINAL.
- 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-48 is/are pending in the application.
 - 4a) Of the above claim(s) 7, 8, 11-26, and 28-48 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-6, 9, 10, and 27 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 - 1. Certified copies of the priority documents have been received.
 - 2. Certified copies of the priority documents have been received in Application No. _____.
 - 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) Interview Summary (PTO-413) Paper No(s). _____
- 19) Notice of Informal Patent Application (PTO-152)
- 20) Other:

DETAILED ACTION

1. Claims 1-48 are currently pending.

Election/Restrictions

2. Applicant's election of Group I, claims 1-27, and antibacterial agents, specifically quinolones and fluoroquinolones for species A in Paper No. 6, dated April 16, 2001 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
3. Claims 7, 8, 11-26, and 28-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.
4. Claims 1-6, 9, 10, and 27 are examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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5. Claim 10 is indefinite because it is not clear how similar or dissimilar the other compounds must be to nalidixic acid, norfloxacin, ciprofloxacin or sparfloxacin and still be encompassed by this limitation.
6. Claim 27 is indefinite because it is not clear how to determine how much licorice or dried root should be added to the composition in accordance with this limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-5 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 5,939,050.

The claims are drawn to a composition that contains *Glycyrrhiza glabra* and anti-bacterial agents.

US '050 teaches an anti-microbial composition that contains *G. glabra* extract and other anti-microbial agents (see claim 1). The *G. glabra* extract contains glycyrrhizic acid (see column 4, lines 34-41).

8. Claims 1-6 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 5,770,217.

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US '217 teaches a composition that contains *G. glabra* and other herbal ingredients. *G. glabra* is present in the composition at 0.25 to 5% (see claim 1). The *G. glabra* contains glycyrrhizic acid (see column 5, line 51).

The other ingredients in the composition are reported to have many properties including antibacterial, antifungal, and antiviral effects (see column 4 line 43 - column 6, line 11).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1, 6, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No 5,770,217.

As stated above, US '217 teaches administering *G. glabra* extract in combination with antibacterial agents. However, US '217 does not specifically teach adding *G. glabra* in the full

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range of amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

10. Claims 1, 5, 6, 9, 10, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,939,050, The Merck Index (Budavari et al. (eds) (1989), 11th edition, Merck & CO., Inc: New Jersey, entry numbers 2315, 6273, and 6617) and US Pat. No. 5,478,829.

The claims are drawn to a composition containing *G. glabra*, nalidixic acid, norflaxacin, ciprofloxacin, and sparfloxacin.

US '050 teaches that *G. glabra* is an anti-bacterial agent.

The Merck Index teaches that nalidixic acid, norfloxacin, and ciprofloxacin are anti-bacterial agents.

US '829 teaches that sparfloxacin is an anti-bacterial agent (see column 1, lines 15-37).

These references show that it was well known in the art at the time of the invention to use *G. glabra*, nalidixic acid, norflaxacin, ciprofloxacin, and sparfloxacin in anti-bacterial compositions. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically

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from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used in anti-bacterial compositions, an artisan of ordinary skill would have a reasonable expectation that a combination of these substances would also be useful in creating anti-bacterial compositions. Therefore, the artisan would have been motivated to combine *G. glabra*, nalidixic acid, norflaxacin, ciprofloxacin, and sparfloxacin into a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See In re Sussman, 1943 C.D. 518; In re Huellmantel 139 USPQ 496; In re Crockett 126 USPQ 186.

The references do not specifically teach adding the *G. glabra* extract in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

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11. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 7:30 to 5:00 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SDC
April 26, 2001



FRANCISCO PRATS
PRIMARY EXAMINER